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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,429	08/29/2001	Jorge H. Capdevila	22000.0110U2	7467

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EXAMINER

VOGEL, NANCY T

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/942,429	Applicant(s) CAPDEVILA ET AL.	
	Examiner Nancy Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 10, 14 and 18 drawn to a method of enhancing the activity of Cyp 4A14, or inhibiting the activity of testosterone, or inhibiting the activity of Cyp 4A12, or inhibiting the activity of human Cyp 4A11, each by administering an agent that enhances the activity of Cyp 4A14, classified in class 435, subclass 189.
- II. Claims 2, 4, 9, 13 and 17 drawn to a method of inhibiting the activity of Cyp 4A14, or enhancing the activity of testosterone, or enhancing the activity of Cyp 4A12, or enhancing the activity of human Cyp 4A11, each by administering an agent that inhibits the activity of Cyp 4A14, classified in class 435, subclass 189.
- III. Claim 5, drawn to a method of enhancing the activity of Cyp 4A12 by a administering an agent that enhances the activity of Cyp 4A12, classified in class 435, subclass 189.
- IV. Claim 6, drawn to a method of inhibiting the activity of Cyp 4A12 by administering an agent that inhibits the activity of Cyp 4A12, classified in class 435, subclass 189.
- V. Claims 7 and 15, drawn to a method of inhibiting the activity of Cyp 4A12 or inhibiting the activity of human Cyp 4A11, by administering an agent

that inhibits the activity of testosterone, classified in class 435, subclass 189.

- VI. Claims 8 and 16, drawn to a method of enhancing the activity of Cyp 4A12, and enhancing the activity of human Cyp 4A11 by administering an agent that enhances the activity of testosterone, classified in class 435, subclass 189.
- VII. Claim 11 drawn to a method of enhancing the activity of human Cyp 4A11 by administering an agent that enhances the activity of human Cyp 4A11, classified in class 435, subclass 189.
- VIII. Claim 12, drawn to a method of inhibiting the activity of human Cyp 4A11 by administering an agent that inhibits the activity of human Cyp 4A11, classified in class 435, subclass 189.
- IX. Claims 19 and 20, drawn to a method of identifying an agent capable of enhancing or inhibiting the activity of Cyp 4A14, classified in class 435, subclass 4.
- X. Claims 21 and 22, drawn to a method of identifying an agent capable of inhibiting or enhancing the activity of Cyp 4A12, classified in class 435, subclass 4.
- XI. Claim 23 and 24, drawn to a method of screening for an agent capable of inhibiting or enhancing the activating effect of testosterone on the activity of Cyp 4A12, classified in class 435, subclass 4.

- XII. Claims 25 and 26, drawn to a method of screening for an agent capable of inhibiting or enhancing the activating effect of testosterone on the activity of human Cyp 4A11, classified in class 435, subclass 4.
- XIII. Claims 27 and 28, drawn to a non-human transgenic mammal, or mouse, comprising a gene encoding murine Cyp 4A14 which has been inactivated or completely deleted, classified in class 800, subclass 14 or 18.
- XIV. Claims 29 and 30, drawn to a non-human transgenic mammal, or mouse, comprising a gene encoding murine Cyp 4A12 which has been inactivated classified in class 800, subclass 14 or 18.
- XV. Claims 31 drawn to a non-human transgenic mouse comprising a gene encoding murine Cyp 4A14 which has been inactivated, and having a endogenous murine Cyp 4A12 gene that has been inactivated or deleted, and has a copy of the human Cyp 4A11 gene has been introduced into the genome of the mouse, classified in class 800, subclass 18.
- XVI. Claim 32 drawn to a transgenic mouse comprising a gene encoding murine Cyp 4A14 which has been inactivated, and having a endogenous murine Cyp 4A12 gene that has been inactivated or deleted, and has a copy of the human Cyp 4A11 gene has been introduced into the genome of the mouse and has been inactivated, classified in class 800, subclass 18.

- XVII. Claim 33, drawn to a method identifying an agent capable of reducing hypertension comprising administering a test agent to the mouse of claim 28, classified in class 800, subclass 3.
- XVIII. Claim 34, drawn to a method of identifying an agent capable of reducing hypertension comprising administering a test agent to the mouse of claim 31, classified in class 800 subclass 3
- XIX. Claim 35, drawn to a method of treating hypertension comprising inhibiting testosterone activity, classified in class 435, subclass 189.
- XX. Claims 36 and 38, drawn to a method of treating hypertension comprising enhancing Cyp 4A14 activity, classified in class 435, subclass 189.
- XXI. Claims 37, drawn to a method of treating hypertension comprising inhibiting Cyp 4A11 activity, classified in class 435, subclass 189.
- XXII. Claims 39-43, drawn to a method of identifying a subject having an increased susceptibility for developing hypertension, comprising detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group XIII and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XIII can be used as a source of DNA for hybridization studies.

Inventions of Group XV and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XV can be used as a source of DNA for hybridization studies.

The inventions of Group XIII-XVI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups I-XII and XVII-XXII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-XII and XVII-XXII comprise steps which are not required for or present in the methods of the other groups: administering an agent that enhances the activity of Cyp 4A14 (Group I), administering an agent that inhibits the activity of Cyp

4A14 (Group II), administering an agent that enhances the activity of Cyp 4A12 (Group III), administering an agent that inhibits the activity of Cyp 4A12 (Group IV), administering an agent that inhibits the activity of testosterone (Group V), administering an agent that enhances the activity of testosterone (Group VI), administering an agent that enhances the activity of human Cyp 4A11 (Group VII), administering an agent that inhibits the activity of human Cyp 4A11 (Group VIII), contacting Cyp4A14 with a test agent and determining if the activity of Cyp 4A14 is enhanced or inhibited (Group IX), contacting Cyp 4A12 with a test agent and determining if activity of Cyp 4A12 is enhanced or inhibited (Group X), contacting Cyp 4A12 with a test agent in the presence of testosterone and determining if the activity of Cyp 4A12 is inhibited or enhanced (Group XI), contacting human Cyp 4A11 with a test agent in the presence of testosterone and determining if the activity of human Cyp 4A11 is inhibited or enhanced (Group XII), administering a test agent to a transgenic mouse comprising a gene encoding murine Cyp 4A14 which has been inactivated or deleted and comparing the blood pressure to a mouse to which no test agent has been administered (Group XVII), administering a test agent to a mouse comprising genes encoding murine Cyp 4A14 and Cyp 4A12 which have been inactivated or deleted, and wherein a human Cyp 4A11 gene has been introduced, and testing blood pressure (Group XVIII), inhibiting testosterone activity (Group XIX), enhancing Cyp 4A14 activity (Group XX), inhibiting Cyp 4A11 (Group XXI), and detecting a mutant Cyp4A11 polypeptide or nucleic acid (Group XXII). The end result of the methods are different: enhanced activity of Cyp 4A14 (Group I), inhibited activity of Cyp 4A14 (Group II), enhanced activity of Cyp 4A12

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(Group III), inhibited activity of Cyp 4A12 (Group IV), inhibited activity of testosterone (Group V), enhanced activity of testosterone (Group VI), enhanced activity of human Cyp 4A11 (Group VII), inhibited activity of human Cyp 4A11 (Group VIII), isolation of an agent capable of affecting the activity of Cyp 4A14 (Group IX), isolation of an agent capable of effecting the activity of Cyp 4A12 (Group X), isolation of an agent cable of affecting the activating effect of testosterone on the activity of Cyp 4A12 (Group XI), isolation of an agent capable of affecting the activating effect of testosterone on f the activity of human Cyp 4A11 (Group XII), isolation of an agent capable of reducing hypertension (Groups XVII and XVIII), treating hypertension by inhibiting testosterone activity (Group XIX), treating hypertension by enhancing Cyp 4A14 activity (Group XX), treating hypertension by inhibiting Cyp 4A11 activity (Group XXI), and identification of a subject having increase susceptibility for developing hypertension (Group XXII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups XIII-XVI and Groups I-XII, XVII-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups XIII-XVI are not used in the methods of Groups I-XII, XVII-XXII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to the following patentably distinct species of the claimed invention: a method of identifying a subject having an increased susceptibility for developing hypertension, comprising detecting a mutant Cyp 4A11 which is Cyp 4A11/W126-R, Cyp 4A11/R231-C, Cyp 4A11/M369-R, or Cyp 4A11/L509-F.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 39 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

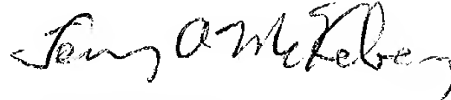
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv


TERRY MCKELVEY
PRIMARY EXAMINER